
SUMMARY OF SAFETY & EFFICACY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Eagle Vision, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis Tennessee, 38133 USA	MAY 2 2006
OFFICIAL CORRESPONDENT	Jeff Cobb Vice President, RA/CA/QA Eagle Vision, Inc. 8500 Wolf Lake Drive, Suite 110 Memphis Tennessee, 38133 USA Tel: (901) 380-7000 FAX: (901) 380-7001 e-mail: jeff@eaglevis.com	
TRADE NAME:	EagleVision Gellanserts	
COMMON NAME:	Temporary Punctum Plugs Temporary Inserts	
CLASSIFICATION NAME:	Plug, Punctal	
DEVICE CLASSIFICATION:	Class II per 21 CFR § 886	
PRODUCT CODE	86 (LZU)	
PREDICATE DEVICES:	EagleVision Gellanserts are substantially equivalent to: <ul style="list-style-type: none">▪ K850649 ABSORBABLE INTRACANALICULAR COLLAGEN IMPLANT▪ K890919 TEMPORARY INTRACANALICULAR COLLAGEN IMPLANT▪ K895342 COLLAGEN IMPLANTS FOR THE LACRIMAL EFFICIENCY TEST▪ K897190 LOOK TEMPORARY INTRACANALICULAR COLLAGEN IMPLANT▪ K946357 COLLAGEN INTRACANALICULAR PLUG▪ K013613 SOFT PLUG ABSORBABLE PLUG-SA▪ K020882 SHARPOINT ULTRAPLUG EXTENDED WEAR PLUG▪ K022043 SMARTPLUG MODEL 500▪ K030300 OPAQUE HERRICK LACRIMAL PLUG	

SUMMARY OF SAFETY & EFFICACY

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

EagleVision Gellanserts are intended to temporarily block tear drainage by occlusion of the canaliculus. EagleVision Gellanserts are made of a hydrophilic, resorbable material, and are designed to expand only laterally after insertion into the canaliculus, so that only one size is needed to occlude most patients' lacrimal systems. The EagleVision Gellanserts are designed to expand and fit virtually all patient anatomies from 0.3mm up to 1.1 mm, so multiple inserts in one canaliculus are generally not necessary. There are five inserts per sterile pouch, so that one EagleVision Gellansert can be placed in each punctum with one additional EagleVision Gellansert in case one is dropped or mishandled.

INDICATION FOR USE:

The EagleVision Gellansert® has the same primary intended use as the predicated devices. The EagleVision Gellansert is intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Determine the potential effectiveness of permanent occlusion,
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Increase retention of ocular medications
- Temporarily treat contact lens intolerance secondary to dry eye, and
- Treat dry eye after surgery.

CONTRAINDICATIONS:

EagleVision Gellanserts have the same primary contraindications as the predicate devices. EagleVision Gellanserts are contraindicated for use in patients with known gellan sensitivity, infectious conjunctivitis, dacryocystitis, inflammation of the eyelid, infected eyes, or epiphora.

MATERIALS:

Gellan is an anionic polysaccharide that gels in the presence of cations such as Sodium (Na^+) and Calcium (Ca^{++}). It is soluble in water, and hydrates rapidly in solution. As the gel hydrates, it also expands (up to 500% or more depending on the concentration of gellan and the strength of the ionic bonds). After hydration, the gellan becomes pliable and malleable to conform to the inside of the volume that constrains it (assuming the volume is less than or equal to the physical size of the gel in its hydrated state). 21 CFR 172.665 states that gellan gum may be safely used in food, in accordance with the following conditions:

1. The additive is of a high molecular weight, produced from *Pseudomonas elodea* (*P. elodea*) by a pure culture fermentation process, and purified by recovery with isopropyl alcohol (IPA).
 2. The strain of *P. elodea* is non-pathogenic and nontoxic in man and animals
-

SUMMARY OF SAFETY & EFFICACY

3. The additive is produced by a process that renders it free of viable cells of *P. elodea*
4. The additive meets the following specifications:
 - a. A tough worm-like gel forms when a 1% solution is extruded through a wide bore pipet into a 10% Calcium Chloride bath
 - b. A firm gel forms when 0.50 grams of Sodium Chloride is added (under 80 °C heat for 1 minute) to the 1% solution above.
 - c. Residual IPA does not exceed 0.075%
5. The additive is intended for use in accordance with good manufacturing practices

Gellan is also listed in:

- USP-National Formulary (NF 22) 71010-52-1
- The Toxic Substances Control Act (TSCA) Chemical Substances Inventory
- The Canadian Non-Domestic Substances List (NDSL)
- The European Inventory of existing Commercial Chemical Substances (EINECS)

In addition to the above, Toxicological Studies performed by the gellan manufacturer demonstrate the following Safety Data for gellan:

- Oral dosage – rat LD50: >5,000 mg/kg
- Inhalation –rat LC50 (4-hr): >6mg/L (nominal)
- Eye irritation – rabbit: nonirritating
- Skin irritation – rabbit: nonirritating
- No SARA Hazard notifications are applicable for this material

DESIGN FEATURES:

The design features of the EagleVision Gellanserts raise no new issues of safety or effectiveness. EagleVision Gellanserts consist of a length of rigid, hydrophilic, resorbable material. Common forceps (jewelers, collagen or otherwise) are used in the insertion of EagleVision Gellanserts. The EagleVision Gellanserts are provided sterile. EagleVision Gellanserts expand to accommodate different patient physiologies and achieve occlusion of the punctum and/or canaliculus. This device is sub-punctal, to limit contact and possible irritation to the eye due to abrasion.

Comparison of the design features of the EagleVision Gellanserts to the predicate devices are given in the table below.

SIMILARITIES AND DIFFERENCES OF EAGLEVISION GELLANSERTS TO PREDICATE DEVICES

A comparison of the similarities and differences between EagleVision Gellanserts to the predicate devices is given in the following table.

COMPARISON OF EAGLEVISION GELLANSERTS TO PREDICATE DEVICES

Elements	EagleVision Gellanserts	Absorbable Intracanalicular Collagen Implant (K850649)	Temporary Intracanalicular Collagen Implant (K890919)	Collagen Implant for the Lacrimal Efficiency Test (K895342)	Look Temporary Intracanalicular Collagen Implant (K897190)	Collagen Intracanalicular Plug (K946357)	Soft Plug Absorbable Plug-SA (K013613)	SharPoint UltraPlug Extended Wear Plug (K020882)	SmartPlug Model 500 (K022043)	Dissolvable Opaque Herrick Lacrimal Plug (K030300)
Indications	<i>Temporary punctal or canalicular occlusion may be used to temporarily block tear drainage by the occlusion of the canaliculus in order to:</i> <ul style="list-style-type: none"><i>Determine the potential effectiveness of permanent occlusion,</i><i>Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,</i><i>Increase retention of ocular medications</i><i>Temporarily treat contact lens intolerance secondary to dry eye, and</i><i>Treat dry eye after surgery.</i>									
Design Characteristics										
Intracanalicular Punctum Plug	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Intended Duration	Temporary	7 – 10 days	7 – 10 days	7 – 10 days	7 – 10 days	7 – 10 days	Less than 3 months	180 days	Permanent	180 days
Material	Hydrophilic, dissolvable polymer	Animal Collagen	Animal Collagen	Animal Collagen	Animal Collagen	Animal Collagen	Polyglycolate suture	PCL Monofilament Synthetic Absorbable Suture	Thermosensitive Hydrophobic Acrylic Polymer	PCL or PDO or glycolic acid & trimethylene carbonate copolymer
Packaging	Tyvek/Poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch	Tyvek/poly pouch
Elements	EagleVision Gellanserts	Absorbable Intracanalicular Collagen Implant (K850649)	Temporary Intracanalicular Collagen Implant (K890919)	Collagen Implant for the Lacrimal Efficiency Test (K895342)	Look Temporary Intracanalicular Collagen Implant (K897190)	Collagen Intracanalicular Plug (K946357)	Soft Plug Absorbable Plug-SA (K013613)	SharPoint UltraPlug Extended Wear Plug (K020882)	SmartPlug Model 500 (K022043)	Opaque Herrick Lacrimal Plug (K030300)
Method of Insertion	Forceps	Forceps	Forceps	Forceps	Forceps	Forceps	Forceps	Forceps	Forceps	Forceps

SUMMARY OF SAFETY & EFFICACY

Method of Removal	Dissolution, Saline irrigation, or Lacrimal probe followed by saline irrigation.	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe	Dissolution, Saline irrigation or Lacrimal probe
Method of Sterilization	EtO Sterilization (EO)	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation	Gamma (γ) Irradiation

CONCLUSION:

Based on the above, the EagleVision Gellanserts are substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2006

Eagle Vision, Inc.
c/o Mr. Jeff Cobb
8500 World Lake Drive, Suite 110
Memphis, Tennessee 38133

Re: K053333

Trade/Device Name: EagleVision Gellanserts
Regulation Number: Unclassified
Regulation Name: Plug, Punctal
Regulatory Class: Class II
Product Code: LZU
Dated: April 18, 2006
Received: April 19, 2006

Dear Mr. Cobb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Jeff Cobb

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "M B Eydelman, MD". The signature is fluid and cursive, with the "MD" at the end being more distinct.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K053333

Device Name: EagleVision Gellanserts

Indications for Use:

The EagleVision Gellansert™ is intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Determine the potential effectiveness of permanent occlusion,
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Increase retention of ocular medications
- Temporarily treat contact lens intolerance secondary to dry eye, and
- Treat dry eye after surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRL, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K053333Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)